LIC LANGFORD IC SYSTEMS, INC	LIC INSTRUMENT PROCESSOR Pre-Market Notification 510(k) K101158 Section XV. 510(k) Summary	Page XV - 1

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MAY - 6 2011

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Preparation Date: April 21, 2011

1.0 CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Pending Name - Class II
Common / Usual Name: Washer – Endoscope and Accessories
Device Classification: 21 CFR § 876.1500, – Endoscope and accessories
Product Code: FEB
Proprietary Name: LIC Instrument Processing System; and
Proprietary Name: Manzi MS10 Sterilant

2.0 PREDICATE DEVICE

The LIC Instrument Processing System (K101158) claims equivalence to the Manzi Mach 1 Instrument Cleaner – Processor System (K060458) found substantially equivalent on 10/12/2006. The predicate device is cleared for use with the MS10 Sterilant concentrate (MEC 0.49% PAA, minimum contact temperature of 120° F for a contact time of 15 minutes) for cleaning and high level disinfecting flexible bronchoscopes used in health care settings by health care workers.

3.0 INDICATIONS FOR USE

The LIC Instrument Processing System consists of the LIC Instrument Processor, the Manzi Detergent MD10, the Manzi Sterilant MS10, and filtered ozonated final rinse water.

The LIC Instrument Processor when used with the Manzi Detergent MD10, the Manzi Sterilant MS10 concentrate (MEC 0.49% PAA, minimum contact temperature of 120° F for a contact time of 5 minutes), and filtered and ozonated final rinse water, is indicated for cleaning and high level disinfection of heat sensitive semi-critical endoscopes used in health care settings by health care workers. Manual cleaning of medical devices (endoscopes) is not required prior to placement in the LIC Instrument Processor.

The Manzi Detergent MD10 concentrate when used with the LIC Instrument Processor is indicated for the cleaning of heat sensitive semi-critical endoscopes used in health care settings by health care workers.

The Manzi Sterilant MS10 concentrate when used in the LIC Instrument Processor is indicated for high level disinfection of heat sensitive semi-critical endoscopes used in health care settings by health care workers.

The filtered ozonated final rinse water generated by the LIC Instrument Processor is indicated for the final rinsing in the LIC Instrument Processor of heat sensitive semi-critical endoscopes used in health care settings by health care workers.

4.0 DESCRIPTION OF THE DEVICE

The LIC Instrument Processing System consists of a LIC Instrument Processor, a proprietary Manzi sterilant, MS10; a proprietary enzymatic Manzi Detergent, MD10; and internally generated filtered ozonated final rinse water. The LIC Instrument Processing System requires no connectors to be attached to the endoscope.

The LIC Instrument Processor is a self-contained stand-alone system designed to clean and provide high level disinfection of semi-critical endoscopes using the MD10 detergent, the MS10 sterilant, and a patented push-pull agitation system. The push-pull agitation system effectively scrubs the interior and exterior surfaces of the semi-critical endoscopes without the use of special connectors. The scope is placed in a processing chamber where it is exposed to a push-pull agitation cleaning cycle that provides cleaning to a protein residual level $\leq 6.4\ \mu g / cm^2$, followed by hot water rinses, a push-pull agitation disinfection cycle that provides high level disinfection of the instrument being processed and final rinses with filtered ozonated water.

The hardware for the LIC Instrument Processor consists of a stainless steel processing chamber, a push-pull agitation pump, an ozonator, a neutralization tank, and a variety of components that are mounted in a movable covered frame. The cleaner-processor system utilizes accessories such as disposable water filters, reusable semi-critical endoscopes trays, baffle inserts, and printer paper.

The LIC Instrument Processor is designed to: (1) be used in accordance with the reprocessing instructions provided in the operator's manual of the instruments being processed, and (2) facilitate the health care facility's compliance with reprocessing guidelines published by SGNA, APIC, AORN, ASGE, CDC, and other professional organizations.

MD10 is a low foaming enzyme chemical detergent packaged in single use containers for attachment to the LIC Instrument Processor. MD10 is intended to be used with the LIC Instrument Processor only.

MS10 is a peracetic acid based liquid chemical sterilant packaged in single use containers for attachment to the LIC Instrument Processor. MS10 is intended to be used with the LIC Instrument Processor.

5.0 COMPARISON TO THE PREDICATE DEVICE

The LIC Instrument Processing System is equivalent in operational principles to the Manzi Mach 1 Instrument Cleaner-Processor System cleared in K060458 10/12/2006. Both devices are intended for high quality cleaning and high level disinfection of flexible endoscopes, use no connectors, operate with the endoscopes in submerged solution, and utilize a detergent and sterilant cleared by the FDA. Both devices process one endoscope at a time. The devices differ in the Indications for Use as described in the table below:

Manzi Mach 1 as Configured in K060458	LIC Instrument Processor
The Manzi Mach 1 Instrument Cleaner Processor System is indicated for use with the MD10 Detergent and the High Level Disinfectant MS10 concentrate (MEC 0.49% PAA, minimum contact temperature of 120° F for a contact time of 15 minutes) for cleaning and high level disinfecting flexible bronchoscopes used in health care settings by health care workers.	The LIC Instrument Cleaner Processor System is indicated for use with the MD10 Detergent and the High Level Disinfectant MS10 concentrate (MEC 0.49% PAA, minimum contact temperature of 120° F for a contact time of 5 minutes) for cleaning and high level disinfecting of heat sensitive flexible endoscopes used in health care settings by health care workers.

6.0 SUMMARY OF NONCLINICAL TESTS FOR THE LIC INSTRUMENT PROCESSOR

6.1 Qualification Testing – FDA Guidance

The LIC Instrument Processing System was tested and found to conform to the requirements of the **"Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer / Disinfectors, and Disinfectors Intended for Use in Health Care Facilities", dated August, 1993"**. The table below identifies the qualifications performed and the results obtained:

Requirement				Results
G..	Performance Data			
	1	Process Parameter Tests		Passed
	2	Simulated Use Tests		Passed
		2.c.	Effectiveness Tests	
		2.c.(1)	Cleaning Efficacy	Passed
		2.c.(2)	Disinfection Efficacy	Passed
		2.c.(3)	Rinsing Efficacy	Passed
		2.c.(4)	Other Tests	Passed
		2.c.(5)	Combined Process	Passed
	3.	In – Use Tests		Passed
H.	Software Documentation			Passed
I.	Toxicological Evaluation of Residues			Passed

6.2 Process Parameter Test

The LIC Instrument Processing System was tested to demonstrate that the device performs as intended. The test results showed that the LIC Instrument Processing System achieves and maintains the specified physical process parameters, automatically aborts the cycle if the specified parameters are not achieved, detects the defined fault conditions, and provides the designated alarms and instructions in the event of fault condition detection.

6.3 Cleaning Efficacy Testing – LIC Instrument Processing System Cleaning Step

The LIC Instrument Processing System's cleaning step was challenged by endoscopes containing both protein loaded soil and TOC loaded soil and tested for cleaning efficacy. The test results demonstrate that the LIC Instrument Processing System when challenged with endoscopes contaminated with a Protein Laden Soil up to 1080 $\mu g/cm^2$ yielded remaining protein levels of < 3.7 $\mu g/cm^2$. The test results also demonstrate that the LIC Instrument Processing System when challenged with endoscopes contaminated with a TOC Laden Soil up to 160 $\mu g/cm^2$ yielded remaining TOC levels of < 1.5 $\mu g/cm^2$.

The LIC Instrument Processing System's cleaning step was also challenged using endoscopes contaminated by clinical endoscopy with naturally occurring soils in in-use testing. The in-use test results demonstrated remaining protein levels < 1.2 $\mu g/cm^2$ after processing through the LIC Instrument Processing System's cleaning step.

6.4 Disinfection Efficacy Testing – LIC Instrument Processing System Disinfection Step

The LIC Instrument Processing System was tested to evaluate its ability to high level disinfect endoscopes contaminated to $\geq 10^6$ microbial loading of Mycobacterium terrae in simulated use testing. The simulated use testing demonstrated that ≥ 6 spore log reduction with no CFUs was achieved with the inoculated endoscope when processed through the disinfection step of the LIC Instrument Processing System.

6.5 Disinfection Efficacy Testing – LIC Instrument Processing System Full Cycle

The LIC Instrument Processing System was tested to evaluate its ability through its full cleaning, disinfecting, and final rinse cycle to high level disinfect endoscopes contaminated to $\geq 10^6$ microbial

loading of Mycobacterium terrae in simulated use testing and to disinfect endoscopes contaminated by clinical endoscopy with naturally occurring soils in in-use testing. The simulated use testing demonstrated that ≥ 6 spore log reduction with no CFUs was achieved with the inoculated endoscopes when processed through the full cycle of the LIC Instrument Processing System. The in-use testing demonstrated that no viable organisms or CFUs were recovered from the clinically used endoscopes following processing through the LIC Instrument Processing System's full cycle.

6.6 Filtered Ozonated Final Rinse Water Efficacy Testing – Microbiological Challenge

Simulated use testing was conducted to demonstrate the efficacy of the Filtered Ozonated Final Rinse Water of the LIC Instrument Processing System. The LIC Filtered Ozonated Final Rinse Water System was challenged where ≥ 10^6 microbial loading was introduced into the Filtered Ozonated Final Rinse Water System and tested after the water was processed to the systems operational specifications. The test results showed a > 6 spore log reduction with no CFUs.

6.7 Toxicological Evaluation of Residues

The safety of residual chemicals remaining on endoscopes after processing in the LIC Instrument Processing System was evaluated. The test results showed that that the LIC Instrument Processing System processing cycle reduces detergent and sterilant residuals to non-toxic levels.

7.0 SUMMARY OF NONCLINICAL TESTS for the MANZI MS10

7.1 Qualification Testing – FDA Guidance

The Manzi MS10 Sterilant was tested to and met the requirements of the current edition of **"Guidance for Industry and FDA Reviewers, Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants / High Level Disinfectants", dated January 3, 2000.** The table below identifies the qualifications performed, the applicable Guidance Section, and the results obtained:

FDA Guidance Requirement		Results
5.4	Potency Test	Passed
5.5	Simulated Use Tests	Passed
5.6	In-Use Tests	Passed
6.0	Biocompatibility	Passed

7.2 Qualification Testing – AOAC Tests

Microbiological Efficacy Summary		
Test Method	Test Organisms	Results
Sporicidal Activity of Sterilants; AOAC Official Method 966.04	Bacillus subtilis Clostridium sporogenes	MS10 is sporicidal
Fungicidal Activity of Sterilants; AOAC Official Method 955.17	Trichophyton mentagrophytes	MS10 is fungicidal
Use-Dilution Method; AOAC Official Method 955.14, 955.15, 964.02	Salmonella choleraesuis Staphylococcus aureus Pseudomonas aeruginosa	MS10 is bactericidal
Virucidal Testing	Poliovirus Type 1	MS10 is virucidal
Quantitative Tuberculocidal Test	Mycobacterium bovis	MS10 is tuberculocidal

8.0 OVERALL PERFORMANCE CONCLUSIONS

The studies demonstrate that the LIC Instrument Processing System is safe and effective for the cleaning and high level disinfection of heat sensitive semi-critical endoscopes within the stated indications for use for the LIC Instrument Processor, the Manzi MS10 Sterilant, and the Manzi Detergent, MD10, and establishes substantial equivalence of the LIC Instrument Processing System to the predicate device identified in Section 2.0 above.

LIC qualification and validation testing has demonstrated that the LIC Instrument Processing System will clean endoscopes to a remaining protein level of < 3.7 µg/cm²; significantly reduce the residual TOC level; high level disinfect endoscopes to reduce the microbial load by greater than 6 logs with no remaining CFUs, and rinse the instrument with filtered ozonated water.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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MAY - 6 2011

Re: K101158
Trade/Device Name: LIC Instrument Processing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FEB
Dated: April 16, 2010
Received: April 26, 2010

Dear Ms. Langford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K#101158 .

Device Name: LIC Instrument Processing System

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Prescription Use ___ _ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101158